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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,402	03/28/2001	Liaohai Chen	S-94,756	5503

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EXAMINER
CEPERLEY, MARY

ART UNIT	PAPER NUMBER
1641	6

DATE MAILED: 11/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,402	CHEN, LIAOHAI	
	Examiner	Art Unit	
	Mary (Molly) E. Ceperley	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *5-10,22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1) Claims 5-20, 22, and 23 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

2) The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3) Claims 1-4 and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation of "chemical moieties" by the reaction of the double bond of one monomer with a double bond of another biomolecule-substituted monomer to form a polymer as shown in Scheme 1 of page 9 of the specification, does not reasonably provide enablement for the preparation of "chemical moieties" by any other type of reaction. Claim 1, as written, includes the cases, for example, in which ***(a)*** the "reaction product" is formed by the reaction of a functional group substituent such as an amino group on the "polyelectrolyte monomer" with a functional group substituent such as a carboxylic acid on the monomer of the "biological agent recognition element – substituted polyelectrolyte monomer" or ***(b)*** the case in which a functional group on the "biological agent recognition element" reacts with a double bond of the "polyelectrolyte monomer". It is further unclear what moiety of either a PEG-biomolecule conjugate or a PEG monomer (specification, page 4, line 27) would react in the process of claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

4) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6) Claims 1 and 3 are rejected under 35 U.S.C. 102(b)/(e)103(a) as being anticipated by or obvious over each of ***a)*** Jou et al (U.S. 5,866,322), ***b)*** Jou et al (U.S. 5,670,381), ***c)*** Prakash et al (U.S. 6,251,866), ***d)*** Wu et al (U.S. 5,166,320), or ***e)*** Schacht et al (U.S. 6,312,727).

a) Jou et al ('322) describes a polymeric ionic monomer (a "polyelectrolyte monomer") which is covalently attached to a specific binding member (BM) (a "biological agent recognition element"). See the structure depicted at col. 16, lines 35-40 and col. 18, lines 50-60 wherein *n* is a repeating unit of 10-50. The product of the reference anticipates or renders obvious the product produced by the process of instant claim 1 in accordance with MPEP 2113. Although the product of the reference may be prepared by one method, for example by conjugating the specific binding member to the pre-formed polymer (col. 10, lines 38-60) while the product of instant claim 1 is prepared by a different method, i.e. polymerization of a biomolecule-substituted monomer with an unsubstituted monomer, the final product in both instances appears to be the same (see MPEP 2113). The method of making a product as recited in a product by process claim does not necessarily patentably distinguish the claimed ***product*** from a prior art ***product*** prepared by a different method.

b) In accordance with the reasoning set forth in ***a)*** above, Jou et al ('381) similarly describes conjugates of a biomolecule with cationic or anionic monomers which anticipate or renders obvious the conjugates of the instant claims. See col. 10, lines 21-42; Ex. 19, c.; col. 56, lines 16-19.

c) In accordance with the reasoning set forth in ***a)*** above, Prakash et al (U.S. 6,251,866) similarly describes a biomolecule-polymer conjugate which anticipates or renders obvious the conjugates of the instant claims. See the structure of col. 8, lines 3-17, A-P-L wherein P is a PEG polymer (a neutral polymer as described in the instant specification at col. 4, line 27), L is the member of a specific binding pair. The open-ended "comprises" language of instant claim 1 does not exclude the presence of additional elements such as the "chemical reagent" (A) or optional spacers (T) of the Prakash et al conjugates.

d) In accordance with the reasoning set forth in ***a)*** above, Wu et al (U.S. 5,166,320) similarly describes a biomolecule-polymer conjugate which anticipates or renders obvious the conjugates of the intstant claims. See claim 1, the conjugate of a) and claim 3 wherein the polycation is polylysine, polylysine being a "polyelectrolyte" polymer.

e) The last structure of Fig. 8 of the Schacht et al describes a biotin-substituted "polyelectrolyte" polymer conjugate which anticipates or renders obvious the conjugates of the instant claims in accordance with the reasoning set forth in paragraph ***6)a)*** above. See also, the "cationic polymers" of col. 7, lines 15-27.

8) Xia et al (J. Phys. Chem. 1993, 97, 4528-4534: abstract) and Chen et al (WO 00/66790: claims 1 and 20) are cited to further show the state of the art.

9) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE at (703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

November 7, 2002

Mary E. (Molly) Ceperley
Primary Examiner
Art Unit 1641